



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|--------------------------|---------------------------|------------------|
| 09/841,264 | 04/24/2001 | Ranjani V. Parthasarathy | 56286USA4A.003 | 5359 |
| 32692 | 7590 | 11/19/2003 | | |
| 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427 | | | | |
| | | | EXAMINER NAFF, DAVID M | |
| | | | ART UNIT 1651 | PAPER NUMBER |

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/841,264 | PARTHASARATHY ET AL. | |
| | Examiner | Art Unit | |
| | David M. Naff | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 25-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/28/02. 6) ☐ Other: _____

Claims in the application are 1-50.

In a response of 8/25/03 to a restriction requirement of 7/28/03, applicants elected Group I claims 1-24 with traverse on the ground that a separate examination of the different groups would require a
5 substantial duplication of work. However, while some duplication may result, this is far out weighted by the undue burden of the additional work required to examine all of the different inventions together because of their differences as pointed out in the restriction requirement. Accordingly, the restriction requirement is
10 adhered to and made final.

Claims 25-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response of 8/25/03.
15 Claims examined on the merits are 1-24.

Applicants request rejoinder of the non-elected claims if claims 1-24 are found allowable. However, the non-elected claims must also be allowable for rejoinder to occur.

20 The copending applications listed in an Information Disclosure Statement have been considered, but have been lined through since applications have not been published and are not listed on U.S. Patents.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The preliminary amendment filed 2/28/02 is objected to under 35
5 U.S.C. 132 because it introduces new matter into the disclosure. 35
U.S.C. 132 states that no amendment shall introduce new matter into
the disclosure of the invention. The added material which is not
supported by the original disclosure is as follows: added figures 2-4.
It is not clear where the specification supports that an incorporated
10 reference is to be used to supply the figures to the present
specification.

Applicant is required to cancel the new matter in the reply to
this Office Action.

Claim Rejections - 35 USC § 103

15 Claims 1, 5-16, 20 and 23 are rejected under 35 U.S.C. 103(a) as
being unpatentable over Park et al (5,861,251) in view of Shultz et al
(6,242,235 B1) and Hayes et al (5,721,123).

The claims are drawn to a composition containing an enzyme which
can be a polymerase, a dye that inactivates the enzyme and a nonionic
20 or zwitterionic surfactant that inhibits inactivation of the enzyme by
the dye. Also claimed is a method of stabilizing an enzyme by
combining the surfactant with the enzyme and dye.

Park et al disclose a PCR reagent mixture containing a
polymerase, a dye and a nonionic surfactant (col 3, lines 1-30). The
25 nonionic surfactant improves reactivity of the PCR mixture.

Art Unit: 1651

Shultz et al disclose stabilizing polymerases with nonionic surfactants (col 6, lines 40-43).

Hayes et al disclose using heat absorptive dyes for enhancing the heating effect of electromagnetic radiation when carrying out the PCR
5 process (col 3, lines 7-36).

It would have been obvious to include in the PCR reagent mixture of Park et al a nonionic surfactant to obtain its function to improve reactivity as taught by Park et al and to obtain its function to stabilize the polymerase as taught by Shultz et al. It would have
5 been further obvious to include in the reagent mixture a heat absorptive dye to obtain its function of enhancing the heating effect of electromagnetic radiation as taught by Hayes et al. The dye of Park et al and/or the heat absorptive dye of Hayes et al would have inherently reduced polymerase activity in the absence of the
10 surfactant. Selecting another surfactant such as a zwitterionic surfactant that functions to stabilize polymerase similar to a nonionic surfactant would have merely required limited routine experimentation and been obvious.

Response to Arguments

15 Applicants urge that the word "dye" does not appear in column 3, lines 1-30 of Park et al. However, "water-soluble dye" is clearly recited at col 3, line 32. It is clear that all of the reagents disclosed by Park et al in col 3 for the PCR are reagents that can be used together in the PCR. Park et al clearly teach that the dye can
20 be used in the presence/absence of the stabilizer which can be the surfactant (col 3, lines 30-35). Therefore, it is clearly obvious from the teachings of Park et al to use the dye and surfactant together since Park et al teach functions of the dye and surfactant that would have made their combination desirable when performing the
25 PCR.

Applicants further urge that the references do not teach that the dye inactivates the enzyme in the absence of the surfactant. However, the dye of Park et al and/or the heat absorptive dye of Hayes et al would have inherently reduced polymerase activity in the absence of
5 the surfactant.

It is granted as urged by applicants that Shultz et al does not disclose a dye and Hayes et al does not disclose a surfactant. However, these references are combined with the Park et al reference which suggests the a combination of dye and surfactant. The
10 references are applied together and must be considered in combination as a whole rather than each alone. The references clearly provide motivation since the result that will be obtained is taught by the references and will be expected.

It is granted as urged by applicants that inherency cannot be
15 used to establish obviousness in a 103 rejection. However, in the present case, inherency is not being used to establish obviousness. Nowhere does the rejection state that the invention is obvious because of the inherency. The rejection states that the invention is obvious for reasons other than the inherency, and the inherency results when
20 performing the obvious invention for the reasons other than the inherency.

Applicants urge that in Example 6, Park et al disclose that bromophenol blue, xylene cyanole, bromocresol red and cresol red did not decrease the level of the PCR. However, the present specification
25 discloses (paragraph bridging pages 8 and 9) that suitable dyes absorb

energy at a wavelength of at least 400 nm. This would appear to include the dyes used by Park et al that are disclosed not to decrease PCR level. Applicants may be using a different method for determining a decrease in enzyme activity due to the dye than used by Park et al
5 for determining a decrease in PCR level. In any event, Park et al disclose that methyl green decreased the PCR level, and the use of this dye in combination with the surfactant would have been obvious.

Claim Rejections - 35 USC § 103

Claims 2-4, 17-19, 21 and 24 are rejected under 35 U.S.C. 103(a)
10 as being unpatentable over the references as applied to claims 1, 5-16, 20 and 23 above, and further in view of Nadeau et al (5,919,630).

The claims require the dye to be a near-IR dye.

Nadeau et al disclose using near-IR dyes as part of a donor/acceptor dye pair for carrying out the PCR (col 9, line 38, and
15 col 2, line 42).

When modifying the PCR reagent mixture of Park et al as set forth above, it would have been obvious to further include in the PCR reagent mixture a near-IR dye to obtain its function in a donor/acceptor dye pair as taught by Nadeau et al.

20 ***Response to Arguments***

Applicants urge that Nadeau et al does not disclose a surfactant. However, Nadeau et al is not applied alone, and a surfactant is suggested by Park et al, as well as Shultz et al.

Double Patenting

Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,617,136 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed composition and method would have been obvious from the claims of the patent that require a composition containing an enzyme such as a polymerase, a nonionic or zwitterionic surfactant and a near-IR dye

Response to Arguments

Applicants state that an appropriate response will be made when allowable subject matter is indicated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

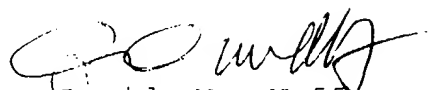
Application/Control Number: 09/841,264

Page 9

Art Unit: 1651

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

5



David M. Naff
Primary Examiner
Art Unit 1651

10 DMN
11/17/03